EXHIBIT D

GenBioPro

GenBioPro, Inc.
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April 13, 2023

The Honorable Robert M. Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Building 32, Room 2346
Silver Spring, MD 20993-0002

Re: ANDA #A091178 (GenBioPro / Mifepristone)

Dear Commissioner Califf:

I am writing regarding GenBioPro's ("GBP") abbreviated new drug application ("ANDA") for mifepristone (No. 091178) and following up on GBP's March 1, 2023 Letter to FDA ("March 1 Letter"), FDA's March 24, 2023 Letter from Center for Drug Evaluation and Research Director Patrizia Cavazzoni, MD ("March 24 Letter") and GBP's April 9, 2023 Letter to FDA ("April 9 Letter").

As you are aware, just before midnight last night, the U.S. Court of Appeals for the Fifth Circuit issued an unpublished order granting in part and denying in part Defendants' Emergency Motion for a Stay Pending Appeal in *Alliance for Hippocratic Medicine v. FDA* ("*AHM*"), No. 2:23-10362 ("*AHM* Fifth Circuit Order"). The *AHM* Fifth Circuit Order granted Defendant's requested stay only as to the district court's "stay" of the 2000 Approval of Mifeprex and denied the stay as to the district court's "stay" of "all subsequent actions," including FDA's approval of GBP's ANDA for mifepristone.

As you are aware, a federal court in Washington state has also enjoined FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative January 2023 Risk Evaluation and Mitigation Strategy under 21 U.S.C. § 355-1 in" 17 states and the District of Columbia. *Washington v. FDA*, No. 1:23-CV-3026-TOR (E.D. Wash. Apr. 7, 2023), ECF No. 80 ("*Washington* Order") at 30.

Given the conflicts between these orders, GBP urgently requests that FDA confirm it will follow all applicable rules and procedures afforded by law and regulation to GBP as the ANDA holder, and that GBP is permitted to continue marketing and selling mifepristone under its 2019 approval and subsequent approved supplements and the operative 2023 REMs. As you know, GBP is not a party to the *AHM* litigation and is thus not bound by the orders in that case. Instead, FDA is the

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regulatory agency that exercises authority over GBP and GBP is seeking much needed clarity from FDA regarding the status of its ANDA and related regulatory approvals.

GBP once again seeks immediate confirmation from FDA of the following requests:

First, please confirm that GBP's ANDA approval remains in effect as currently approved, particularly given that the reference drug upon which GBP's ANDA is based remains approved pursuant to the *AHM* Fifth Circuit Order reversing the district court's stay. Given that the reference drug has not been withdrawn for safety or efficacy reasons—and indeed, remains fully approved—GBP's ANDA must also remain approved. 21 U.S.C. § 355(j)(6); 21 C.F.R. § 314.151.

Second, please commit that FDA will not withdraw, suspend, or otherwise take action that would impair GBP's ANDA approval and associated rights. Congress vested the authority to stay or suspend an approved drug application *exclusively* in the Secretary of Health and Human Services; Congress also restricted that authority to be used only in extraordinary circumstances. *See* 21 U.S.C. § 355(e). Specifically, under the Federal Food, Drug, and Cosmetic Act ("FDCA"), if the Secretary "finds that there is an imminent hazard to the public health, he may suspend the approval of [an NDA] immediately." 21 U.S.C. § 355(e). Secretary Becerra has made no "imminent hazard" finding with respect to mifepristone.

Third, please confirm that FDA will issue a non-enforcement order declaring that it will not, under any circumstances, take any enforcement action against GBP or its distributors, customers, and partners based on the *AHM* Order's purported "stay" of GBP's ANDA. This includes, but is not limited to, any enforcement action pursuant to 21 U.S.C. §§ 355(a), 331(d), 333(a), and 334(a). A non-enforcement order is particularly appropriate here because there is a direct conflict between two federal courts. *See AHM* District Court Order at 67 ("stay[ing] the effective date" of FDA's approval of GBP's ANDA); *Washington* Order at 30 (enjoining FDA from "altering the status quo and rights as it relates to the availability of Mifepristone under the current operative" REMS in 17 states). These rulings cannot be reconciled, and distributors, doctors, patients, and manufacturers all require guidance.

Fourth, the *AHM* Fifth Circuit Order refused to stay the district court's order relating to several subsequent regulatory decisions related to the REMs that apply to mifepristone. GBP requests immediate guidance from FDA confirming that mifepristone may continue to be sold under the existing 2023 REMs, which reapproved the safety and efficacy of the drug, until further guidance. Any other outcome creates an untenable situation where mifepristone will become unavailable to the public and thus presents a grave threat to public health.

Fifth, as GBP previously proposed, an immediate remedy for the existing conflict between the two federal court orders is for FDA to issue an interim final rule with immediate effect, declaring that FDA's approval of GBP's ANDA shall remain effective pending public comments and any further judicial review of the *AHM* Order. Such a rule is authorized by the FDCA and the APA. *See* 21 U.S.C. § 371(a); 5 U.S.C. § 553(b)(B).

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Thank you for your consideration of this matter of pressing public importance. In light of the exigency here, we respectfully request FDA's response by 10:00 a.m. EDT on Friday, April 14, 2023. If you or your staff have questions, please do not hesitate to reach out.

Sincerely,

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